REMARKS

Claims 1-6, 9-11 and 32-36 are pending in the Application. Claims 1 and 11 have been amended. Support for the amendments can be found in paragraph [0034] of the published application, which states in part, "Energy treatment device 22 may be a medical probe, a catheter, a balloon-catheter, as well as other devices commonly known in the art that are smooth enough to pass easily through blood vessels and heart valves." The amended language of the claims does not expand the scope of the claims, and as such, no further search by the Examiner is believed to be necessary.

Claims 1 and 11 are independent.

On page 2 of the Office Action, Claims 1-6, 9-11, and 32-36 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Regarding independent Claims 1 and 11, the Examiner states, "the specification at no point discloses that "the pressure in the expandable membrane during ablation exceeds the target pressure, and is between approximately 3 to 20 psi," (Office Action, Page 2)(Note: Claims 1 and 11 have been amended to recite "5 to 20 psi"). Applicants' disagree, and respectfully refer the Examiner's attention to paragraphs [0053]-[0055] of the published application. Paragraph [0053] describes an inflation phase, where coolant "is injected to inflate balloon 23 in order to ***provide sufficient mechanical force for inflation***." Paragraph [0054] describes a transition phase, "which allows the flow of refrigerant to enter and exit the catheter tip while at the same time controlling the balloon pressure in order to ***keep the balloon inflated and in place***." Paragraph [0054] further recites, "ablation is already initiated but the pressure switch controls the balloon pressure until

refrigerant flow alone ***maintains the balloon open*** and above atmospheric pressure." Paragraph [0055] explicitly recites, "[d]uring the ablation phase, refrigerant is injected...the refrigerant pressure can be varied from 0 psig to approximately 760 psig."

As such, the specification clearly describes initially inflating the balloon, then maintaining the inflation of the balloon during subsequent phases by increasing and/or adjusting the coolant pressure in the balloon to prevent the balloon from collapsing. Moreover, the amended claimed range of "5 to 20 psi" falls within the range described in the specification. As such, the specification does indeed disclose the claimed subject matter, and a withdrawal of the rejection under 35 U.S.C. §112 is respectfully requested.

On page 3 of the Office Action, Claims 1, 2, 9, and 32-34 are rejected under 35 U.S.C. §102(b) as being anticipated by Droegemueller, U.S. Patent No. 3,294,628. In order to anticipate a claim, a reference must disclose each and every element of the claim. Independent Claim 1 has been amended to state, "positioning the expandable membrane within a portion of a cardiovascular system." Droegemueller fails to disclose or even suggest use of the disclosed device "within a portion of a cardiovascular system," and to the contrary, explicitly discloses an apparatus "for cryogenic necrosis of the entire functional ***uterine endometrium*** in one application and with complete coverage. A flexible bladder is inserted into the ***uterus*** and cryogenic fluid at slightly above atmospheric pressure is circulated through the bladder,"(Col. 2:32-37)(emphasis added). Droegemueller unambiguously discloses a "less expensive sterilization of human females" by necrosing portions of the uterus, which fails to involve placement of any portion of the device "within a portion of a cardiovascular system" as stated in Applicants' amended Claim 1.

Moreover, independent Claim 1 further states, "controllably inflating the expandable membrane to at least a ***predetermined target pressure***," and "ablating a desired tissue region, wherein the pressure in the expandable membrane during ablation ***exceeds the target pressure***." Droegemueller discloses a balder contacting the uterus, where the pressure of the bladder "should preferably be ***maintained*** at or about 2 or 3 p.s.i. to avoid any possible risk of injury to the patient,"(Col. 3:58-62)(emphasis added). This sole reference to bladder pressure explicitly recites ***maintaining*** a pressure, and makes no mention of exceeding that pressure whatsoever. Maintaining a single bladder pressure during operation is not "controllably inflating the expandable membrane to at least a ***predetermined target pressure***," and "ablating a desired tissue region, wherein the pressure in the expandable membrane during ablation ***exceeds the target pressure,***" as stated in Applicants' Claim 1.

In addition, Droegemueller specifically recites a pressure range of 2 to 3 psi "to avoid any possible risk of injury to the patient." As such, according to Droegemueller, to increase the pressure significantly beyond this range would pose a risk to the patient. In addition, the uterine device may only need to be inflated to "insure firm contact with the tissue" of the uterus (Col. 3:58-59), and as such, a lower pressure may be sufficient. With a device positioned within a portion of a cardiovascular system, as stated in Claim 1, an increased inflation or target pressure may be required to overcome constricting blood vessel walls, blood pressure, and the like. As such, the specified range of 2 to 3 psi disclosed in Droegemueller uterine device cannot anticipate the range of 5 to 20 psi for a device "positioned within a portion of a cardiovascular system" as stated in Claim 1.

Accordingly, as Droegemueller fails to disclose "positioning the expandable membrane within a portion of a cardiovascular system," "controllably inflating the expandable membrane to at least a predetermined target pressure," or "ablating a desired tissue region, wherein the pressure in the expandable membrane during ablation exceeds the target pressure, and is between approximately 5 to 20 psi," as stated in Applicants' Claim 1, the rejection is unsupported by the art, and a withdrawal of the rejection is respectfully requested. Moreover, Claims 2, 9, and 32-34 are believed to be allowable as they depend from amended independent Claim 1.

On page 5 of the Office Action, Claims 3, 6, and 11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Droegemueller ('628) in view of Yamaguchi, U.S. Patent No. 5,433,740. Claims 3 and 6 are believed to be allowable as they depend from amended independent Claim 1. As to Claim 11, to establish a prima facie case of obviousness, three basic criteria must be met, one of which is that the prior art reference (or references when combined) must teach or suggest all the claim limitations. Claim 11, as amended recites in part, "positioning the expandable membrane within a portion of a cardiovascular system." As discussed above with respect to Claim 1, Droegemueller fails to disclose or even suggest use of the disclosed device "within a portion of a cardiovascular system," and to the contrary, explicitly discloses an apparatus "for cryogenic necrosis of the entire functional ***uterine endometrium*** in one application and with complete coverage. A flexible bladder is inserted into the ***uterus*** and cryogenic fluid at slightly above atmospheric pressure is circulated through the bladder,"(Col. 2:32-37)(emphasis added). Yamaguchi similarly fails to disclose placement of an expandable membrane "within a portion of a cardiovascular system," and to the contrary, specifically discloses "treatment of the esophagus" with a balloon (Col. 4:61).

Claim 11 further recites, in part, "controllably inflating the expandable membrane...to a predetermined target pressure in order to provide sufficient mechanical force against the desired tissue region," and "ablating the desired tissue region , wherein the pressure in the expandable membrane during ablation exceeds the target pressure." Dreogemueller discloses a single static range to which the bladder is inflated, as discussed above, and fails to disclose "controllably inflating the expandable membrane...to a predetermined target pressure," and "ablating the desired tissue region , wherein the pressure in the expandable membrane during ablation exceeds the target pressure," as stated in amended Claim 11. Yamaguchi similarly fails to disclose any such steps of inflation and/or ablation and their corresponding pressures whatsoever.

As Droegemueller, either alone or in combination with Yamaguchi, fails to disclose each and every element of amended Claim 11, no prima facie case of obviousness has been made. Accordingly, a withdrawal of the rejection is respectfully requested.

On page 7 of the Office Action, Claims 4 and 5 are rejected under 35 U.S.C. §103(a) as being unpatentable over Droegemueller ('628), in view of Yamaguchi ('740), and further in view of Edwards, U.S. Patent No. 6,258,087. Claims 4 and 5 are believed to be allowable as they depend from amended independent Claim 1.

On page 7 of the Office Action, Claim 10 is rejected under 35 U.S.C. §103(a) as being unpatentable over Droegemueller ('628), in view of Stern, U.S. Patent No. 5,443,470. Claim 10 is believed to be allowable as it depends from amended independent Claim 1.

On page 8 of the Office Action, Claims 3, 35, and 36 are rejected under 35 U.S.C. §103(a) as being unpatentable over Droegemueller ('628) in view of Joye, U.S. 2002/0045894

A1. Claims 3, 35, and 36 are believed to be allowable as they depend from amended independent Claim 1.

For all of the above reasons, the claim objections are believed to have been overcome placing Claims 1-6, 9-11 and 32-36 in condition for allowance, and reconsideration and allowance thereof is respectfully requested.

The Examiner is encouraged to telephone the undersigned to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

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